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EXAMINER

ORTIZ RODRIGUEZ, CARLOS R

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

22



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 14

Application Number: 10/036,618  
Filing Date: December 21, 2001  
Appellant(s): CLASBRUMMEL ET AL.

Steven H. Noll  
For Appellant

**MAILED**

**JUN 03 2004**

**Technology Center 2100**

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/22/04

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**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying that there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The Examiner agrees with the statement of the status of amendments contained in the brief. The amendment after final rejection filed on 3/22/04 has been entered.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

The Examiner agrees with the statement in the brief. It should be noted that this section "Grouping of Claims" is not in the proper order as required by 37 CFR 1.192(c).

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

4,436,684	White	3-1984
6,007,243	Ergun et al.	12-1999
6,285,902	Kienzle, III et al.	9- 2001

**(10) Grounds of Rejection**

As necessary and due to the arguments presented in the appellant's brief the Examiner provides further rationale in support of the rejection set forth in prior Office Action, Paper No. 10.

The following discussion of the ground(s) of rejection are applicable to the appealed claims and is the Examiner's ultimate position:

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over White U.S Patent No. 4,436,684 in view of Kienzle, III et al. U.S. Patent No. 6,285,902.

Regarding claim 1, White et al. discloses a method for preparing an anatomical implant (see col. 2 lines 13-14 and col. 1 lines 7-9), comprising the steps of: in a medical intervention procedure, generating a three-dimensional dataset (see col. 1 lines 10-12) of body tissue (see col. 1 lines 46-50 also see col. 24 lines 44-46) of a subject exhibiting a fault to be corrected by an implant (see col. 1 lines 59-65) from a series of two dimensional projections of the body tissue obtained from respectively different projection directions(see col 2 lines 63-68 and col 3 24-28); by moving a x-ray source and a radiation receiver around the body tissue(see col 8 lines 53-58); and in said medical intervention procedure, preparing said implant adapted for introduction into said subject from said three-dimensional dataset (see col 2 lines 14-22).

The apparatus disclosed by White et al. provides for generating three-dimensional dataset from two dimensional projections and preparing the implant from the three-dimensional dataset as specified above, but, White et al. fails to clearly disclose that the apparatus utilized has the shape of a C-arm.

However, Kienzle, III et al. discloses an apparatus that has the shape of a C-arm (a movable C-arm x-ray apparatus) operable intra-operative(during surgery, see col 1 lines 30-32 and col 4 lines 39-41), and moving the x-ray source and a radiation receiver on a C-arm around the subject (see fig 1 and fig 7 elements 115 and 116 also see col 8 lines 14-23).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

Since a variety of instruments with different shapes that generate three-dimensional dataset from two dimensional projection(the instruments utilized by White et al. and Kienzle, III et al. are examples) are known in the art related to imaging body parts, one of ordinary skill in the art would have been motivated to modify the shape of the apparatus disclosed by White et al. with the Kienzle, III et al. reference in order to obtain a smaller and more flexible C-arm shape apparatus(see col 7 lines 57-67) that will perform more accurately in a surgery room(intra-operatively) as suggested by Kienzle, III et al(see col 5 lines 14-20). It is also known that C-arm shape instruments are preferably utilized in surgery rooms as disclosed in Kienzle, III et al(see col 4 lines 5-15).

Regarding claim 2, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising acquiring a three-dimensional dataset which represents a bone structure of said subject(see col 9 lines 63-65 and col 10 lines 50-54 and also see fig.10).

Regarding claim 3, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising preparing said

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implant with an automated device which is supplied with said three-dimensional dataset (see col 2 lines 14-22 also see fig 8a).

Regarding claim 4, White discloses an apparatus for preparing an anatomical implant (see col 2 lines 13-14 and col 1 lines 7-9),  
during a medical intervention procedure, generating a three-dimensional dataset (see col 1 lines 10-12)  
of body tissue (see col 1 lines 46-50 also see col 24 lines 44-46)  
of a subject exhibiting a fault, to be corrected with an implant (see col 1 lines 59-65),  
by obtaining a series of two-dimensional projections of the body tissue from respectively  
different projection directions(see col 2 lines 63-68 and col 24-28)  
having a moving x-ray source and said radiation detector thereon, around the body tissue(see col 8 lines 53-58);  
and an implant-producing device which produces said implant from said three-dimensional dataset, during a medical intervention procedure(see col 2 lines 14-22 also see fig 8a).

The apparatus disclosed by White et al. provides for generating three-dimensional dataset from two dimensional projections and preparing the implant from the three-dimensional dataset as specified above, but, White et al. fails to clearly disclose that the apparatus utilized has the shape of a C-arm.

However, Kienzle, III et al. discloses an apparatus that has the shape of a C-arm (a movable C-arm x-ray apparatus) operable intra-operative(during surgery, see col 1 lines 30-32 and col 4 lines 39-41),

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and moving x-ray source and a radiation receiver on a C-arm shape instrument around the subject (see fig 1 and fig 7 elements 115 and 116 also see col 8 lines 14-23).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

Since a variety of instruments with different shapes that generate three-dimensional dataset from two dimensional projection(the instruments utilized by White et al. and Kienzle, III et al. are examples) are known in the art related to imaging body parts, one of ordinary skill in the art would have been motivated to modify the shape of the apparatus disclosed by White et al. with the Kienzle, III et al. reference in order to obtain a smaller and more flexible C-arm shape apparatus(see col 7 lines 57-67) that will perform more accurately in a surgery room(intra-operatively) as suggested by Kienzle, III et al(see col 5 lines 14-20). It is also known that C-arm shape instruments are preferably utilized in surgery rooms as disclosed in Kienzle, III et al(see col 4 lines 5-15).

Regarding claim 5, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said dataset represents a bone structure, and wherein said implant is adapted to replace said bone structure (see col.3 lines 24-31 also see col.24 lines 40-43).



Regarding claim 6, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said implant-preparing device is an automated device which is supplied with said three-dimensional dataset and automatically prepares said implant therefrom (see col 2 lines 14-22 col. 9 lines 29-40 and also see fig 8a).

3. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over White U.S. Patent No. 4,436,684 and Kienzle, III et al. U.S. Patent No. 6,285,902 in view of Ergun et al. U.S. Patent No. 6,007,243 .

Regarding claims 7-10, White in combination with Kienzle, III et al. discloses all the limitations of base claims 1 and 4. But, White in combination with Kienzle, III et al. fail to clearly specify rotating the C-arm approximately 190°.

However, Ergun et al. discloses the C-arm having an angulation axis and an orbital axis and rotating approximately 190° around the angulation/orbital axis (see col 5 lines 58-67 and col 6 lines 1-21 and fig 1, 2,3).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and Kienzle, III et al. and modifying it with the invention disclosed by Ergun et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms with the ability to move or rotate to desired positions are commonly used in the medical area in order to provide flexibility in positioning the C-arm as disclosed by Ergun et al.

**(11) *Response to Argument***

It should be noted that the brief does not present an argument under a separate *heading* for each issue on appeal(37 CFR 1.192(c)(8)), but separate arguments are presented for claims 1-6 (see appeal brief starting page 5 ending in page 9) and claims 7-10 (see appeal brief starting in page 9 and ending in page10), respectively.

**Arguments for claims 1-6**

**Argument (page 6 lines 4-19 of the appeal brief):** The White reference does not teach intra-operatively obtaining a 3D dataset.

It should be noted that the reference relied on for the “intra-operatively” (e.g., during surgery) feature is Kienzle, III et al. not White because Kienzle, III et al. discloses a small X-ray C-arm shape instrument which due to its C-arm shape and size provides access to the patient by a surgeon (during surgery- see Kienzle, III et al. col 4 lines 39-41), thus creating more flexibility, as stated in the rejection above.

The White reference does disclose obtaining 3D dataset of a region of subject in which an implant is to be implanted(see col 2 lines 19-20), and does teach producing the implant(see col 2 lines 21-22), but due to its shape would not be convenient for use during a surgery. Hence, the shape of the X-ray instrument disclosed by the White reference was modified to include the shape of the X-ray C-arm instrument disclosed by Kienzle, III et al. to provide for the intra-operative (during surgery) feature, as stated in the rejection above.

**Argument (last paragraph of page 6 of the appeal brief):** The White reference clearly does not disclose or suggest method steps or apparatus components which can even serve as a starting point to obtain 3D dataset during a medical intervention procedure involving intra-operative steps.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. It should be noted that the reference relied on for the "intra-operatively" feature is Kienzle, III et al. not White because Kienzle, III et al. discloses a small X-ray C-arm shape instrument which due to its C-arm shape and size provides access to the patient by a surgeon(intra-operatively), thus creating more flexibility, as stated above.

**Argument ( page 7 lines 5-13 of the appeal brief):** The Kienzle, III et al. reference is physically incapable of producing a three-dimensional dataset of a subject.

It should be noted that the reference relied on for producing *three-dimensional dataset* is the White et al. reference not the Kienzle, III et al. reference. Kienzle, III et al. is particularly relied on for the *C-arm shape* characteristic of the X-ray instrument providing flexibility in a surgery room.

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**Argument (last paragraph of page 7 of the appeal brief):** The device disclosed in the Kienzle reference would not even be considered by a person of ordinary skill in the art as appropriate for being operable in an attempt to produce a 3D image.

The Examiner points out that the reference relied on for producing a three-dimensional dataset is the White et al. reference not the Kienzle, III et al. reference. Kienzle, III et al. is particularly relied on for the C-arm shape characteristic of an C-arm X-ray system which provides flexibility in a surgery room.

**Argument (page 8 lines 5-9 of the appeal brief):** The Kienzle, III et al. reference could not be modified to generate 3D dataset to produce an image for monitoring the progress of a medical interventional procedure.

The Examiner points out that the Kienzle , III et al. is not being modified to provide for the generation of a 3D dataset. The Kienzle, II et al. is particularly relied on for the C-arm shape characteristic of the C-arm X-ray instrument (which provides flexibility in a surgery room) in order to modify the White reference to include the C-arm shape. For further clarification, the invention being modified to include the C-arm shape is the White reference not Kienzle, II et al. modified to generate a 3D dataset.

**Argument (page 9 lines 5-8 of the appeal brief):** The White reference does not allow intra-operative imaging, and does not teach intra-operative generation of the implant, and Kienzle, III et al. is incapable of three-dimensional imaging, intra-operatively or otherwise.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. As stated above, the reference relied on for "intra-operatively" feature is Kienzle, III et al. not White. The reason is because the C-arm shape of the X-ray apparatus disclosed in Kienzle, III et al. allows access to the patient by a surgeon creating more flexibility in a surgery(intra-operatively).

The Kienzle , III et al. is not being modified to generate 3D dataset. White (the primary reference) provides for generating a 3D dataset(see col 2 lines 19-20), so there is no need to modify Kienzle, III et al. to generate a 3D dataset.

**Arguments for claims 7-10**

**Argument (page 9 lines 15-17 of the appeal brief):** The Kienzle, III et al. reference apparatus is incapable of executing the necessary range of angular movements so as to allow the acquisition of the data for the production of a 3D image.

The Examiner points out that the Kienzle, III et al. reference is not relied on for the limitations regarding the "range of movements". The reference relied on for the range of movements is the Ergun et al. reference.

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**Argument (page 10 lines 7-10 of the appeal brief):** The basic knowledge of the production of three-dimensional images using a C-arm apparatus by itself would deter a person of ordinary skill in the field of medical implant design from even considering the teachings of the Kienzle, III et al. reference.

The Examiner points out that the Kienzle, III et al. is particularly relied on for the C-arm shape characteristic of an C-arm X-ray system which provides flexibility in a surgery room in order to modify the White reference to include the C-arm shape, not for the production of three-dimensional images because the White(the primary reference) teaches generating 3D dataset and preparing an implant.

**Argument (page 10 lines 14-20 of the appeal brief):** Simply locating a reference(Ergun) disclosing a C-arm apparatus that is capable of such movement (which Appellants have never denied is known), does not provide a person of ordinary skill in the field of medical implant design with any new insight regarding the production of a medical implant in any context, much less in the context of undertaking data acquisition and production of the medical implant intra-operatively in the same medical intervention procedure.

The reference applied to reject the subject matter introduce in claims 7-10 is Ergun et al.

The features of the production of a medical implant intraoperatively in the same medical intervention was relied on by White in view of Kienzle, III et al. The Ergun et al.

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reference was simply introduced to show another example of a C-arm apparatus  
implementing rotation with swiveling casters (see Ergun et al. abstract lines 9-11).

For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,


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June 1, 2004

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